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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,798	12/12/2001	Valentin Kramer	31567.3	9144
5251	7590	11/28/2006	EXAMINER	
SHOOK, HARDY & BACON LLP INTELLECTUAL PROPERTY DEPARTMENT 2555 GRAND BLVD KANSAS CITY, MO 64108-2613			CHANG, VICTOR S	
			ART UNIT	PAPER NUMBER
			1771	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/017,798

Applicant(s)

KRAMER ET AL.

Examiner

Victor S. Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-22,24-27,32-34 and 37-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-22,24-27,32-34 and 37-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Introduction*

1. Applicants' amendments and remarks filed on 10/30/2006 have been entered. Claims 24 and 25 have been amended. Claim 23 has been cancelled. Claims 19-22, 24-27, 32-34 and 37-42 are active. It should be noted that the identifier of amended claim 25 is non-complaint under 37 CFR 1.121(c). Applicants are reminded that a proper identifier for amended claim is "(currently amended)". For the purpose of expediting the prosecution, the claims are entered. However, applicants should review the amendment requirements, any future deficiencies will result in a non-compliant letter.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

3. Claims 19 and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For claim 19, the recitation "... a first plurality of fibrils interconnecting said first node with a said second node, said **first plurality of fibrils** defining a first group of pores therebetween, said **first group of pores** falling substantially within a **first size range** ..." (emphasis added) appears to be vague and indefinite, because it is unclear what the term "first size range" is referring to "size range of an area containing the first plurality of fibrils" or "size

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range of the first group of pores”? In view of the amendment to claims 24 and 25, the term “first size range” is interpreted as “size range of the first group of pores” for the present Office action. Similarly, the term “second size range” is interpreted as “size range of the second group of pores”. Clarification in claim language is requested.

***Rejections Based on Prior Art***

4. Claims 19-22, 24-27, 32-34 and 37-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwin et al. [US 6039755].

Edwin's invention relates to a tubular expanded polytetrafluoroethylene (ePTFE) microporous graft. The graft has a microstructure of nodes interconnected by fibrils. The nodes are elongated under radial expansion, and are substantially perpendicular to the longitudinal axis of the tubular ePTFE. The fibrils are oriented parallel to the longitudinal axis of the tubular ePTFE material [col. 2, lines 42-49; Figs. 1 and 2].

For claims 19-22, each of the micrographs in Figs. 18D, 21B and/or 21D shows the same general structural features as Fig. 2 of the present application. In particular, applicants are reminded of their statements that Fig. 2 is the basis of the recited structural features in claim 19 [see reply filed 3/3/2005, page 3, and reply filed 10/27/2005, page 7]. Since Edwin shows micrographs of expanded microporous ePTFE membrane having regions in which a plurality of interconnecting fibrils defining different pore sizes in different regions among large nodes and small nodes (intermediate nodes between the large nodes); the pattern of these different regions are repeated; and the nodes are in general elongated and parallel to one another, Edwin anticipates the instant invention as claimed. Regarding the limitation that the article is created by

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forming a mixture of a first resin and a second resin having a different molecular weight than said first resin, and then expanding said mixture, since any polymeric material inherently comprises a distribution of molecular weights, i.e., a mixture of molecules over a range of different molecular weights, Edwin's ePTFE anticipates the expanded mixture as claimed.

For claims 24-27, Edwin shows in Fig. 18D lengths of fibrils for small pores in the range of 2-15 mm, and lengths of fibrils for large pores in the range of 20-50 mm.

For claims 32-34, the microstructures in Figs. 18D, 21B and/or 21D read on the structural features of instantly claimed invention. The terms "first material" and "second material" in independent claim 32 are interpreted as meaning a first and a second "PTFE material" [see specification abstract]. Since Edwin's polymeric PTFE material is inherently distributed over a range molecular weights, Edwin anticipates the terms "first material" and "second material" as claimed. Finally, regarding the use limitation of use, i.e., for blood contact application, since statements of intended use do not serve to distinguish structure over the prior art, it has not been given any patentable weight. See *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974).

Finally, for claims 37-42, since they claim the same scope of limitations of claims 19-22, 24-27 and 32-34, they are also rejected as set forth above.

### ***Response to Amendment***

5. Applicants requested at page 6 to initiate a new appeal by filing a new notice of appeal under 37 C.F.R. § 41.31 and then a new appeal brief under 41.37 which contemplates the

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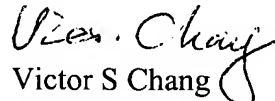
findings made in the latest Office Action. However, only amendment to the claims is submitted, a new appeal brief is absent from the reply filed 10/30/2006.

***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor S. Chang whose telephone number is 571-272-1474. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel H. Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Victor S Chang  
Examiner  
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11/17/2006